REMARKS/ARGUMENTS

Favorable reconsideration of this application in light of the following discussion is respectfully requested.

Claims 19-35 are now pending in this application. Claim 19 is herein amended. Support for the amendment of claim 1 is found at least in the original claims and in Figs. 3A and 3B. Claim 36 is canceled. No new matter is added.

In the outstanding Office Action, claims 19-24 and 28-36 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,646,046 (Fischer). Claims 19-36 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent Publication No. 2003/0054542 (Burns). In response, Applicant herewith amends claim 19. neither amended claim 19, nor any claim depending therefrom, is anticipated by either of the cited references.

Amended claim 19, from which each of claims 20-35 depend, is directed to a quality control device for a blood analyzer using whole blood. The device comprises a means for storing control bloods by refrigeration. The device also comprises means for restoring to temperature the control bloods to a temperature prescribed by the manufacturer of the control bloods. The device further comprises means for stirring for re-suspension of cells, and means for sampling the blood thus prepared. The quality control device is incorporated into the blood analyzer.

The present invention is a quality control device for a blood analyzer using whole blood which is incorporated in the blood analyzer to automatically carry out quality control operations. As explained in the introductory portion of the present specification, a "quality control" is a procedure which consists in checking at least daily that the analyzer is wording properly before carrying out examinations on patients. Specification, par. [0005]. Conventionally, the quality control procedure is carried out manually by an operator by using control blood which are kept in a refrigerator, outside the analyzer. Such control blood

samples are completely distinct from the blood samples to be analyzed. The control bloods are generally presented, with some controls having low, normal, and high values in order to determine the capability of the analyzer for measuring the range of values in a sample of blood. Specification, par. [0007]. The control bloods should be stored under refrigeration at the temperature recommended by the supplier in order to guarantee the expiry date given by the supplier. Before the quality control procedure, the control bloods should be at ambient temperature and should be carefully mixed before being passed through the analyzer.

Until now, the above-described quality control procedure using control bloods has been conducted manually through an operator. To do so, the operator has to remove the control bloods from the refrigerator, leave the control bloods on a draining board for several minutes so that they warm to the ambient temperature, to stir the control bloods carefully, to pass the bloods through the analyzer, to check if the results are within the limits given by the manufacturer, and to replace the bloods in the refrigerator. All these operations are time consuming. Further, the quality of the quality control procedure is highly dependent on the skill of the operator. With the instant invention, a quality control device is incorporated into the blood analyzer, making it possible to carry out the quality control operations in a fully automatic manner. Comprising means for (1) storage by refrigeration for control bloods, (2) restoring to temperature of the control bloods to ambient temperature, (3) stirring for re-suspension of the cells, and (4) sampling of the bloods thus prepared, all incorporated into the blood analyzer, no external refrigerator is required. Further, with this convenience of automatic quality control, a quality control operation may be carried out as frequently as desired without causing inconvenience to the laboratory staff, as the laboratory staff is no longer obliged to conduct a series of manual operations. As discussed below, the cited references do not teach the claimed invention.

Claims 19-24 and 28-36 were rejected as anticipated by Fischer. The Office asserts that Fischer teaches an apparatus and method for automatic analysis of blood samples, with the device including a means for storage by refrigeration, means for heating, means for stirring and means for sampling. Applicant respectfully disagrees. Fischer concerns a method and instrument for automatically performing analysis relating to thrombosis and hemostasis by spectrophotometry. The instrument of Fischer is not a quality control device for control bloods. Instead, the instrument of Fischer conducts different assays to measure hemostasis or thrombosis parameters of samples in test wells using particular reagents. Any disclosure of means for refrigeration, means for heating, means for stirring, and means for sampling disclosed in Fischer is limited to samples and/or reagents, not control bloods. The only disclosure related to quality control in Fischer is related to monitoring the performance of the method and evaluating the validity of the reported data for the sample. Such disclosure is not relevant to the instantly claimed device. Finally, being directed to a different kind of testing, the instrument of Fischer naturally does not comprise means for sampling bloods or re-suspending of the cells.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Failing to disclose the quality control device of claim 19, Fischer cannot anticipate claim 19 or any claims depending therefrom. Applicant respectfully requests withdrawal of these rejections.

Claims 19-36 were rejected as anticipated by Burns. The Office asserts that Burns teaches an apparatus and method for automatic analysis of blood samples. The device includes plurality of stations including a means of storage by refrigeration, means for heating, means for stirring and means for sampling. Again, though, the device in Burns does not

teach the presently claimed quality control device for control bloods incorporated into a blood analyzer. The Burns device is designed for providing specimens to reaction receptacles within an automated analyzer to conduct nucleic acid-based assays. The device works on serum and not on whole blood. The means disclosed therein are for samples and/or reagents and not control bloods. Accordingly, the Burns device teaches nothing about control bloods. Moreover, no means for re-suspension of the cells is disclosed by Burns. Further, there is no means for storing control bloods inside the analyzer. Failing to disclose the quality control device of claim 19, Burns cannot anticipate claim 19 or any claims depending therefrom. Applicant respectfully requests withdrawal of these rejections.

In light of the above discussion, the present application is believed to be in condition for allowance. An early and favorable action to that effect is respectfully requested.

Respectfully submitted,

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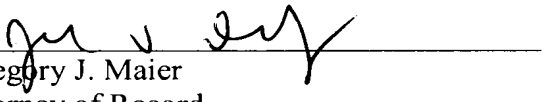

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